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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,421	01/07/2002	Dave Parsons	CV-0290	3678

7590 05/04/2005

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EXAMINER	
PAK, JOHN D	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,421	PARSONS ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-16* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/2005 has been entered.

Claims 9-16 are pending in this application. The restriction (lack of unity) requirement of 11/4/2003 and applicant's election of Group I, claims 9-15, in the reply of 12/8/203 carry over in this RCE. Claim 16 stands withdrawn from further consideration pursuant to the restriction requirement. Claims 9-15 will continue to be examined herein.

Applicant's amendment of 2/9/2005 is noted. As a result, applicant is advised of the following claim interpretation.

Claim 9 language	**Claim interpretation**
An iodine preparation composition suitable for use on wounds comprising an iodide source, *held separately from an oxidant and a buffer*, so that when the iodide source, the oxidant and the buffer are combined at the point of use	Reads on a composition that contains only iodide. There is no requirement that the buffer and oxidant must be **present** in the claimed invention. The language, "held separately" reads on being held separately, like in a separate warehouse or a separate country, or any other degree of separation. The language, "when the iodide source, the oxidant and the buffer are combined" also fails to necessarily require those ingredients in combination. The term "when" can mean "if." Such

↪ Continued

Claim 9 language – continued	Claim interpretation – continued
	claim language does not go so far as to necessarily require the "if," i.e. require the combination for what is being claimed.
the buffer would maintain the pH of the combined composition at between pH 4.5 and pH 6 and that iodine would be generated at a physiologically acceptable dose and rate	Since the claim reads on a composition that contains only iodide, this language is merely descriptive of a buffer that would function in a certain manner. Since the claim is open to a composition containing only an iodide, the buffer feature does not distinguish the claim within that claim scope.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bentley et al. (US 5,128,136).

Bentley et al. explicitly disclose a 3-compartment wound healing system to separately hold three different types of components. The first compartment holds a collagen gel material and a buffer, wherein the buffer will provide a pH in the range of 5.5 to 7.5 when all three compartment contents are added together (column 6, lines 30-44 and 50-55). The second compartment holds potassium iodide and citric acid (column 6, lines 45-46). The third compartment holds potassium iodate (column 6, lines 56-57). See also column 6, lines 58-68; claims 6-9. Example 2 on column 9 shows

examples of 0.37 wt% potassium iodide (equivalent to 22.5 mM), 0.75 wt% potassium iodide (equivalent to 45 mM), and 1.49 wt% (equivalent to 90 mM).

Based on the claim interpretation set forth above, applicant's claims 9 and 13-15 are anticipated by Bentley et al. As explained above, claim 9 reads on a composition that contains only an iodide source. Even if it could somehow be argued that the oxidant and the buffer are required, both such components are in fact disclosed by Bentley et al. The buffer and pH language in claims 9 and 13 are met since Bentley explicitly discloses buffered pH 5.5 as part of the 5.5 to 7.5 pH range. That iodine is generated by Bentely's wound healing system is without question since the iodine generating system is explicitly taught (column 5, lines 21-49).

The feature, "held separately from **an** oxidant" is met by Bentlely et al. because the iodate (which is "an oxidant") in Bentley et al. is held separately from the iodide.

The feature, "iodine would be generated at a physiologically acceptable dose and rate" is met by Bentley et al. since their composition is for treating open skin wounds (paragraph bridging columns 5 and 6).

Applicant's remarks concerning Bentley's teachings have been given due consideration, but they were deemed unpersuasive. Applicant's argument about the pH of Bentley's disclosure is plainly in error. Bentley's explicit disclosure of pH 5.5 is squarely within applicant's claim range. Applicant's argument about a controlled release of iodine does not recognize the reality of the claim language. No matter what

applicant *thinks* is being claimed, what is actually being claimed is a simple composition containing only an iodide source. See the above claim interpretation discussion.

For these reasons, the claims are found to be anticipated.

Claims 9-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Martindale[1].

Martindale explicitly discloses solutions of potassium iodide and sodium iodide that are pharmaceutical grade. See entries for potassium iodide and sodium iodide on pages 972 and 973, respectively. Myriad therapeutic uses including use for cutaneous lymphatic sporotrichosis are disclosed (see p. 972, column 2, second full paragraph).

As explained above, the claims read on a preparation composition that contains only an iodide source. A description such as "held separately" does not necessarily require the presence of another ingredient. A description such as "when ... combined" also does not necessarily require the presence of another ingredient. The claims are merely open to addition of other ingredients, which, "when" or "if" added in sufficient amounts, would produce the claim-recited features[2]. However, since applicant has

[1] Martindale The Extra Pharmacopoeia, 30th ed., 1993, pages 972-73.

[2] The Examiner offers this further analysis.
Claim 1. An aspirin composition comprising aspirin held separately from an aqueous solution.
Claim 2. The aspirin composition of claim 1 characterized in that the combined composition would produce 50 mg of dissolved aspirin per day.

→ Continued

chosen to submit claims that only require a separately held iodide source, i.e. not the subsequently combined composition, the claims do not patentably distinguish over Martindale's prior art iodide solutions. The feature "suitable for use on wounds" is met by Martindale's teaching of myriad therapeutic uses including use for cutaneous lymphatic sporotrichosis (p. 972, column 2, second full paragraph). Such a composition would be so "suitable" on "wounds" since wounds are broad enough to encompass lesions caused by cutaneous lymphatic sporotrichosis. The claims are thereby anticipated.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

It is the Examiner's position that applicant's claim language is similarly problematic as the above example illustration. A textbook aspirin pill teaching would anticipate both claims 1 and 2 since the claims do not actually require the combination of aqueous solution and aspirin. Being held separately is a truism for stand-alone products. At some concentration/volume of aqueous solution and at some number/fraction of prior art aspirin pills, the claim 2 feature would be met. The claims are therefore anticipated by a textbook teaching of aspirin pill. Applicant's fact situation is analogous. Only the iodide source is required. Therefore, the other claim features do not serve to further distinguish the invention.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600